UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,161	12/08/2003	Marco Serra	MDE-002C1	2317

42532 7590 02/12/2007

PROSKAUER ROSE LLP
ONE INTERNATIONAL PLACE 14TH FL
BOSTON, MA 02110

EXAMINER	
VO, HAI	

ART UNIT	PAPER NUMBER
1771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,161	SERRA ET AL.	
	Examiner	Art Unit	
	Hai Vo	1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The art rejections based on Mumick et al (US 5,969,052) have been withdrawn in view of Applicants' arguments. Mumick is concerned with swollen particles for binding fibrous material into an integral structure wherein the integral structure is readily dissolved in the water so that the absorbent product is flushed away after use. As such, swollen particles in combination with a fibrous material could not provide the mechanism for regulating the temperature of an object in contact with the integral structure.
2. The art rejections based on Bashan (US 3,900,030) in view of Zadini et al (US 5,609,586) are maintained.
3. The art rejections based on over EP 0 301 753 are maintained.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 58-69, and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bashan (US 3,900,030) in view of Zadini et al (US 5,609,586). Bashan

discloses a tampon comprising an open cell foam matrix containing hydrogel particles in an amount from 15 to 30% by weight (abstract). The tampon is made from hydrophilic open celled polyurethane foam. Bashan does not specifically disclose the gel particles that expand when a temperature of a fluid in contact with the gel particles is below a phase transition temperature of the gel particles and that contract when the temperature of the fluid in contact with the gel particles is above the phase transition temperature of the gel particles. However, it appears that Bashan uses the open cell foam containing hydrogel particles as Applicants, therefore, it is not seen that the tampon would have performed differently than the material of the present invention in terms of the expansion and contraction in response to the temperature of the fluid to which the gel particles are exposed. Bashan does not specifically disclose the device is used in a wet suit. However, it has been held that a recitation with respect to the manner in which a claimed material is intended to be employed does not differentiate the claimed material from a prior art tampon satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Bashan does not specifically disclose the catamenial tampon comprising a neoprene layer. Zadini, however, discloses a catamenial device comprising a layer 103, a tampon 104 and an expandable member 105 made from neoprene. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the catamenial tampon having an expandable neoprene layer motivated by the desire to provide sealable closure of vaginal canal.

7. Claims 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bashan (US 3,900,030) in view of Zadini et al (US 5,609,586) as applied to claim 58 above, in view of Mumick et al (US 5,969,052). Bashan does not disclose the hydrogel particles made from N-tert-butylacrylamide and NiPAm. Mumick, however, the use of N-tert-butylacrylamide and NiPAm monomers in the sanitary napkins. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the hydrogel particles made from N-tert-butylacrylamide and NiPAm monomers in the foam layer of Bashan because these gel particles exhibit adequate tensile strength and retain their structural integrity when in contact with the body fluid.

8. Claims 58-65, 67-69, 71, and 73-75 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 0 301 753. EP'753 discloses a wound dressing comprising a backing, and an open cell foam matrix containing hydrogel particles in an amount from 20 to 40% by weight (abstract, column 5, lines 40-45, figures 3 and 4). EP'753 does not specifically disclose the gel particles that expand when a temperature of a fluid in contact with the gel particles is below a phase transition temperature of the gel particles and that contract when the temperature of the fluid in contact with the gel particles is above the phase transition temperature of the gel particles. However, it appears that EP'753 uses the open cell foam containing hydrogel particles as Applicants, therefore, it is not seen that the tampon would have performed differently than the material of the present invention in term of expanding and contracting in

response to the temperature of the fluid to which the gel particles are exposed. EP'753 does not specifically disclose the device is used in a wet suit. It has been held that a recitation with respect to the manner in which a claimed material is intended to be employed does not differentiate the claimed material from a prior art tampon satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Accordingly, it is the examiner's position that EP'753 anticipates or strongly suggests the claimed subject matter.

9. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 301 753 as applied to claim 58 above, and further in view of Jensen (US 5,571,080). EP'753 discloses a surgical dressing comprising a foam substrate, a fluid impervious backing and a binder being incorporated into the fibrous substrate (abstract, figures 3 and 4). EP'753 does not specifically disclose the fluid impervious backing made from neoprene rubber. Jensen, however, discloses a surgical dressing comprising a fibrous substrate, a fluid impervious backing wherein the backing is made from neoprene rubber (claim 8). Hence, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use neoprene rubber as the backing layer of the surgical dressing because such is intended use of the material and Jensen provides necessary details to practice the invention of EP'753.
10. Claims 70 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 301 753 as applied to claim 58 above, and further in view of Mumick et al (US 5,969,052). EP'753 does not disclose the hydrogel particles made from N-tert-butylacrylamide and NiPAm. Mumick, however, the use of N-tert-butylacrylamide

and NiPAm monomers in the sanitary napkins. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the hydrogel particles made from N-tert-butylacrylamide and NiPAm monomers in the foam layer of EP'753 because these gel particles exhibit adequate tensile strength and retain their structural integrity when in contact with the body fluid.

Response to Arguments

11. The art rejections based on Bashan in view of Zadini have been maintained for the following reasons. Applicants argue that Bashan and Zadini are primarily concerned with the tampons with swellable polymers that act to plug off flow through the tampon once optimal loading has occurred, to prevent menstrual fluid from leaking. That is completely different from the problem to be solved in the present invention. Applicants then conclude that Bashan and Zadini do not teach the gel material for regulating the surface temperature of an object having its surface in contact with gel material. The examiner respectfully disagrees. Bashan discloses a tampon comprising an open cell foam layer containing hydrogel particles. Bashan meets all the limitations as set forth in the claims, therefore, it is not seen that the tampon would have performed differently than the material of the present invention in terms of the expansion and contraction in response to the temperature of the fluid to which the gel particles are exposed. It seems from the claim, if one meets the structure recited, the properties must be met or Applicant's claim is incomplete. This is in line with *In re Spada*, 15 USPQ 2d 1655 (1990) which holds that products of identical chemical composition can not have mutually exclusive properties.

Applicants have reiterated positions taken with respect to the other rejections, namely Bashan and Zadini in view of Munick, the examiner's comments set forth above are equally pertinent in support of these rejections as well.

12. The art rejections based on EP'753 been maintained for the following reasons. Applicants argue that EP'753 is primarily concerned with wound dressing having a foam impregnated with the water absorbing composition. The wound dressing is designed to prevent the escape of the swollen particles from the dressing, which could give rise to cross-infection. That is completely different from the problem to be solved in the present invention. Applicants then conclude that EP'753 does not teach the gel material for regulating the surface temperature of an object having its surface in contact with gel material. The examiner respectfully disagrees. EP'753 discloses a wound dressing comprising an open cell foam layer containing hydrogel particles. EP'753 meets all the limitations as set forth in the claims, therefore, it is not seen that the wound dressing would have performed differently than the material of the present invention in terms of the expansion and contraction in response to the temperature of the fluid to which the gel particles are exposed. It seems from the claim, if one meets the structure recited, the properties must be met or Applicant's claim is incomplete. This is in line with *In re Spada*, 15 USPQ 2d 1655 (1990) which holds that products of identical chemical composition can not have mutually exclusive properties.

With regard to the rejections based on EP '753 in view of Jensen and the rejections based on EP '753 in view of Mumick, the examiner has provided a

detailed analysis as to why the claimed invention is not patentable in view of EP'753 under Section 102/103. The examiner incorporates those arguments by reference. Thus, the art rejections are sustained.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on Monday through Thursday, from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (571) 272-1478. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hai Vo

HV

HAI VO
PRIMARY EXAMINER